

TEXT REMINDERS IN PYREXIAL PAEDIATRIC PATIENTS (TRIPPP)

A RANDOMIZED CONTROLLED PILOT STUDY

by

Zunaid Mohamed

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Supervisors: Tyson Welzel

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DECLARATION

I, Zunaid Mohamed, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been , is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purposes of research either the whole or any portion of the contents in any manner whatsoever.

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Signed by candidate

Date

13/02/2020

DEDICATION

My parents, Raschid and Faaika Mohamed

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SECTION A: LITERATURE REVIEW

LITERATURE REVIEW

The objectives of this literature review are to

- 1.) Evaluate the discharge process in an Emergency Centre setting.
- 2.) Determine if the use of text messaging adds value to patient care delivery and clinical outcome.
- 3.) Explore concerns associated with the Emergency Centre evaluation of paediatric patients with fever – the intended cohort of patients under consideration.

An electronic search, of the Pubmed, Clinical Key and Google Scholar databases was conducted limited to English articles published prior to 30 April 2019.

Titles, abstracts and articles were scanned and reviewed for relevance to the study objectives and excluded if not considered applicable. All levels of evidence were taken into consideration with preference given to meta-analysis, systematic reviews and randomised controlled trials, if available.

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LITERATURE REVIEW

Student: Dr Zunaid Mohamed
MHMZUN001

Supervisor: Dr Tyson Welzel

This Literature Review is a partial fulfilment of the MPhil degree

Introduction

Transitions in care – including at the point of discharge from a hospital - may potentially place patients in a position of increased risk and vulnerability.(1)

This is recognised to be of particular concern for paediatric patients, compounded by the fact that no widely accepted or used standards of care for paediatric discharge exist. Current research and quality improvement efforts to optimize care transitions in children are considered an essential contributor to reducing post hospitalization morbidity and improving family centred care. (2)(3)

Care transitions are also considered especially challenging during the discharge process from the Emergency Centre. Effective patient education and follow-up arrangements may be compromised in the frequently fast paced, high patient volume environment often characterised by interruptions and distractions thus increasing the risk of medical error. This is further complicated by shift working healthcare providers who are required to treat unfamiliar patients of varying clinical acuity who present for care.(1)(4)(5)

1.) Evaluation of the discharge process in an Emergency Centre setting.

The Emergency Centre discharge process, as a point of transitioning care from caregiver to patient, is frequently associated with inadequate communication and coordination, often resulting in a brief interaction in which forms and prescriptions are provided. This may leave patients and caregivers feeling uncertain about their diagnosis and care plan. Healthcare providers without previous knowledge of the patient , working in a distraction filled and time limited environment are often required to interact with patients that are anxious to leave, and who may be less inclined to ask questions.(1)

A study analysing audiotaped Emergency Centre discharge instructions found that only half of all patients received information regarding the anticipated course of their illness, and even fewer received advice regarding important return criteria.(6)

Furthermore, the time period for delivering discharge information has been reported as being as brief as two minutes and may frequently be provided without determining patient comprehension. Poor recall has been noted to occur immediately after being discharged, implying that it is not merely a result of forgetting the detail over time.(4)(7)

At particular risk of insufficient comprehension, are those patients with limited health literacy and where a language barrier exists. Misunderstanding or poor recollection of instructions by caregivers may specifically put children at increased risk for post discharge adverse events and outcomes.(1)(3)

There are additional challenges and complexities regarding discharge instructions in the paediatric population when compared to adult, including errors in dosing of medication, poor medication adherence and poor follow-up attendance - as described in a systematic review of the literature conducted by Glick, et al. in 2017, which explored caregiver and parental comprehension and adherence to discharge instructions. Further research into improving the management of discharge planning for paediatric patients was advised.(3)

Poor patient comprehension of their Emergency Centre visit is not just limited to the discharge information but may also include all other aspects of care provided - including consultation and tests.(7)

However, even when discharge instructions may be regarded as being adequate, patients may struggle to understand and recall instructions and often do not comply with appointments or prescribed treatments, thus placing them at increased clinical risk. (4)

The Emergency Centre discharge period, however, may also provide a unique opportunity to offer a summary of the visit, deal with any concerns or questions, and educate patients on safe homecare. In this way, improve healthcare related outcomes and patient satisfaction while contributing to a reduction in overall healthcare related costs.(1)(4)

Ideally, the discharge process needs to be efficient, reliable and standardized, while at the same time allowing for a degree of flexibility to accommodate patients from a diversity of backgrounds in terms of language, literacy and culture. A multistage collaborative quality improvement process was initiated by Limpahan, Baier, Gravenstein, et al., Healthcentric Advisors for the Quality Improvement Organisation for the State of Rhode Island in the United States, in order to more clearly delineate practice guidelines for Emergency Centre care transitions. The intention was to provide best practices for improved communication at the point of transition from the Emergency Centre to the community. Included in the recommendations for safe care transitions was effective education and the provision of written instructions prior to discharge.(4)

Elements that needed to be included were the diagnosis, any new or changed medication, specific “red flags” that should prompt the patient to seek medical attention, the recommended follow-up plan and whom the patient should call. Education should be provided verbally to the patient, family or caregiver and should be included as written discharge instructions together with the necessary contact information required.(4)

Discharge information should contain content that is structured and presented in a manner incorporating written and visual cues which may assist with enhancing comprehension and recall. It is essential that instructions are easily understood and worded in the patient’s language. Furthermore, comprehension of the content needs to be verified prior to the patient leaving the Emergency Centre in order to address areas of confusion and misunderstanding.(1)

Aspects not yet characterised and defined are the manner and timing of the discharge process, as well as the relationship between the discharge process and patient outcomes. Attempts at improving discharge information have to date yielded only moderate overall success. In order to address this challenge and mitigate the associated risks, new and innovative ways at improving the Emergency Centre discharge process and in particular discharge communication - have been suggested and evaluated.(1)

The successful implementation of higher quality and improved electronic discharge instructions when compared to hand written instructions have been reported. Attempts at investigating the possibilities of electronically enhancing transitions of care have extended to email and also specifically to the currently most pervasive wireless device, the mobile phone, including its use of text messaging, smartphone applications and patient portals.(8-10)

2.) The incorporation and use of text messaging in the delivery and outcomes of clinical patient care

Over the recent decades mobile phone messaging has evolved to become an integral means of communication worldwide, with access extending to 95 percent of countries globally, including significant expansion of networks and services being experienced in emerging nations. According to a Pew Research Centre survey published in 2015, mobile phone ownership in Southern Africa had experienced exponential growth in particular within South Africa where nine-in-ten adults were reported to own a cell phone. Thirty four percent of South Africans own a smart phone allowing access to the internet and smartphone applications. Ninety five percent of South Africans report that the most popular mobile phone activity is sending text messages.(11-12)

It has been reported that individuals, irrespective of gender, age, socioeconomic, educational and ethnic background, display an interest in using mobile technology to receive healthcare information from providers. Subsequently, mobile technology has been used in order to promote health and prevent disease. Its use has extended to voice calling, internet connectivity and messaging by text or video. Periodic prompts and reminders have been demonstrated to be an effective method for reinforcing healthy behaviours.(9)(11)

When compared to alternative means of communication mobile phone usage offer numerous advantages. It is inexpensive, ubiquitous, mobile, offers direct immediate access and is less likely to be misplaced in comparison to printed material.(11)

A 2019 systematic review describing discharge communication practices in paediatric emergency care, reported that the majority of studies describing these interventions were found to investigate methods for improved information sharing with a specific focus on the evaluation of various modes of education delivery. Almost half of these studies utilised technology enabled tools such as video or interactive websites which were found to positively influence patient education and adherence to recommended guidelines.(13)

Mobile technology smartphone applications may also be utilised to provide patient education and advice. However, despite surveys suggesting significantly high levels of trust in the modality by patients, its use as a medical device remains unregulated.(10)

An increased use of patient portals have been encouraged as part of the Meaningful Use program which was initiated in order to incentivise enhanced and appropriate electronic health record implementation in the United States. These technological advances may be used to facilitate improved patient access to health information and its functionality potentially includes the ability to send and receive health related notifications.(10)

As mobile phone users become increasingly inundated with various notifications, ignoring or failing to act on the information delivered may occur as a result of alert fatigue. This phenomenon is more extensively studied among healthcare providers in the setting of medical computer-based decision support but may be equally applicable to patients who are required to act on mobile alerts.(10)

It has been reported that approximately 60% of patients with mobile phones prefer to receive health related information with text messaging, internet and email and these may thus may be considered as possible first lines of intervention. Only 20% of patients were willing to

receive health information with audio and video files. These trends may change as the ability to access these functions become more commonplace.(14)

Although studies describing interventions utilising social media platforms like We Chat and the use of video discharge instructions can already be found in the literature, text messaging, as a mobile phone modality used in healthcare, remains more extensively researched.(15 – 17)

Text message reminders are increasingly being utilized in the healthcare setting in order to improve medication compliance, to ensure appointment attendance, to facilitate appropriate follow up, as well as direct care management, such as in diabetes self-management, smoking cessation and weight loss.(11)

A 2018 systematic review of more than 2000 articles related to the use of text messaging in healthcare conducted by Schwebel and Larimer found that almost all studies suggested an improvement in patient medical and appointment compliance. Additional benefits reported, included ease of use, low cost and rapid and automated delivery. The majority of patients found the text reminder to be acceptable and minimal risks were reported. (17)

A systematic review of text messaging as a tool for behaviour change in healthcare done by Cole Lewis and Kershaw found that 8 of the 9 sufficiently powered studies supported text messaging as a tool for behaviour change. At this stage, although the review supports its use in behaviour change, the actual combination of text message factors – such as it's frequency and duration of intervention, has not yet been determined. (11)

According to a review by Kannisto, et al. there is currently no recommended “dose” for text message reminders (i.e. the number of messages and how frequently they are sent) and the timing of text message reminders (i.e. the actual time sent), with many studies (22%) basing the above on the patients personal needs, for example relating the timing of the message with when medication should be taken or when a scheduled appointment was due. Seventeen percent of the studies reviewed did not report the time of sending the text message. (18)

In this setting, where the parent still acts as an intermediary, Kharbanda, et al. performed a qualitative analysis of parental readiness to receive text messages as a reminder to return for immunizations that were due. The study found this reminder to be well accepted by parents. This was in a diverse population in an urban setting in which they preferred this method to phone and mail reminders. A randomised control trial performed by the same investigators found an increased rate of return for influenza vaccinations in those patients that had received text message reminders compared with usual care. (19)(20)

A retrospective cohort study conducted at a tertiary care paediatric Emergency Centre found that most (75%) return visits, were for a problem that either had not improved or had worsened, and were unscheduled. Children were more likely to be younger than 2 years old with infectious (45%) and respiratory disease (16%) as the most common causes. They concluded that developing systems which encouraged patients to return to the Emergency Centre when necessary may be an efficient contributor to medical error reduction and prevention of adverse outcomes in paediatric patients. (21)

3.) Emergency Centre evaluation of paediatric patients with fever - the intended cohort of patients under consideration.

Fever is the most frequent presenting complaint in children, resulting in 20% of Emergency Centre visits and it remains one of the most frequent reasons for hospital admission in the paediatric population. In Sub-Saharan Africa, fever represents 6-30% of all practice visits. (22 - 24)

Rather than being considered a primary illness or disease, fever should be regarded as a beneficial physiological response aiding recovery and it is a symptom of an underlying disorder, often an infection. (25 - 27)

In most instances the cause is viral, self-limiting and benign. And patients generally recover rapidly without significant intervention. The most common problems that these patients experience are discomfort and dehydration. The majority of cases require only reassurance with effective return precautions. However, among these many patients, there may exist a few children without an easily identified focus of infection – who may in reality have a serious bacterial infection that is challenging to diagnose due to subtle symptoms and non-specific, difficult to detect clinical signs often leading to late recognition. (22)(25)(28 - 29)

These five to ten percent of children with fever have a more serious underlying illness which is especially common in the younger patient, who also runs an increased risk of rapid clinical deterioration. Thus, the exact same presentation could herald a significant life-threatening condition. (23)(30)(31)

In South Africa, serious bacterial infection, such as meningitis, bacteraemia, pneumonia, urinary tract infection, bacterial enteritis, cellulitis and orthopaedic infections remain among the common causes of death in children. (22)(26)(31)(32-33)

A 2016 systematic literature review by Kiemde et al. reported *E.coli*, *Strep. pneumoniae*, *Salmonella* spp. and *Staph. aureus* to be the most prevalent bacteria species isolated in children under the age of five years presenting with non-malaria febrile episodes in Sub Saharan Africa. Specific clinical and epidemiological data pertaining to serious bacterial infection in the private South African healthcare setting is not available at this stage. (24)

Although fever need not be investigated on every occasion, it is vital to identify and further assess those patients who – as a result of an underlying bacterial focus of infection may be at risk of serious illness or clinical complications. This early identification of patients with serious bacterial infection and subsequent workup with aggressive treatment and timely antibiotic therapy would contribute to a reduction in the associated morbidity and mortality. (23)(30)(34)

Numerous clinical aids such as the “Traffic Light System”, - as described in the NICE Clinical Guidelines, the Rochester, Boston and Philadelphia Criteria developed in the 1990’s, and various treatment algorithms, including guidelines and recommendations published for use by community health workers in a South African setting, have been developed to in order to risk stratify febrile children. (22)(23)(26)

A retrospective cohort study evaluating the accuracy of the Traffic Light System - which is a decision rule utilising clinical examination findings - found the system to have moderate

sensitivity but low specificity for the detection of bacteraemia, urinary tract infection and pneumonia. The Rochester, Boston and Philadelphia Criteria developed for infants aged 30 - 90 days have incorporated laboratory investigations with clinical history and examination findings. They have all been found to perform similarly well.(22)(35)

The use of laboratory variables such as infection markers like procalcitonin, white cell count (WCC) and C- Reactive Protein (CRP) remains an ongoing area of research and may face issues of turnaround time in an EC setup. Of those available, procalcitonin appears to offer greater reliability than CRP and WCC, but there remain limitations in this setting. The tests should be used together with history, examination and other diagnostic tests, including X-ray and urinalysis, to determine a probability estimate of bacterial infection.(28)

A 2016 study performed at the Steve Biko Academic Hospital in Pretoria, South Africa concluded that biomarkers (Full Blood Count, CRP and procalcitonin) did not seem to predict the severity or source of infection in pyrexial children presenting for care. Furthermore, no correlation was found related to their duration of hospitalization. They concluded that clinical suspicion of serious infection and appropriate action are as valuable as extensive testing. The study, however, had a relatively small sample size and thus this viewpoint could not be confirmed.(36)

In resource constrained settings, specialist paediatric expertise and investigations to support diagnosis may not be readily available. And where they are, the diagnosis remains difficult. A probability estimate of bacterial infection is made by the physician incorporating diagnostic tests and decision modifiers such as practice setting, ease and reliability of follow-up and patient demographics - in the decision making process. (28)(29)(37)

Despite the availability of practice guidelines, variability in adherence to the protocols has been reported implying a lack of compliance. In addition, the risk of evolving illness in children who don't meet the emergent criteria also remains present.(38)(42)(40)

Additional factors confounding decision making, when assessing children with fever, especially in a South African setting, include the patient's immunization status, immune status - in view of the high prevalence of HIV infection, the broad spectrum of potential aetiologies and presence of malnutrition, which has been reported to increase the severity, case fatality and mortality of common infections. (28)(40)(41)(42)(43)

It has been reported that in emerging nations, children with HIV/AIDS also frequently tend to be malnourished. Due to a poorly developed immune system, the clinical presentation observed in these children tends to be more persistent and severe, often not responding as well to standard treatment regimes. Pneumonia, ear infection, gastroenteritis and tuberculosis occur frequently.(44)

Tuberculosis bacteraemia is responsible for 34, 8 % of sepsis in HIV positive patients. For many patients though, the causative organism may remain unidentified or alternatively there may be multiple co infecting organisms implicated.(43)

It is thus also essential to be able to have a strong grasp of the local epidemiology of fever, which provides guidance for empiric antibiotic regimes, immunization schedules and clinical decision making.(45)

Conclusion

Children who present with fever with no obvious source of infection may potentially have a serious bacterial infection as an underlying cause, requiring further investigation and treatment. Serious bacterial infections are not always easily or promptly recognised and diagnosed, and are associated with significant morbidity and mortality.(23)(28)(29)(30)

There exists a variation in application of current risk stratification criteria and proposed guidelines for the evaluation of fever in children which are influenced by, among other factors, practice setting and ongoing research involving biomarkers.(28)(36)(38)(39)(40)

The focus in the literature to date has been on the detection of serious bacterial infections at the initial consultation rather than on encouraging return for re-evaluation as a safety net in case of non-recognition. It has been suggested that developing systems which encourages patients to return to the emergency department when necessary may contribute to the reduction in medical error and the prevention of adverse outcomes in paediatric patients. (21)

Improved discharge communication – including the provision of return criteria - may be considered essential for the delivery of high quality emergency care. However, the relationship between the discharge process and patient care outcomes – including associated and preventable morbidity and mortality, have until now remained undetermined. (2)(3)(4)(7)

Although widely researched, data pertaining to the use of text message reminders incorporated in healthcare delivery, within developing countries, remains sparse .Given the reported benefits and its relative cost effectiveness, text messaging may prove to be a compelling intervention for the advancing of healthcare education delivery and improving patient care outcomes.(11)

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SECTION B: RESEARCH ARTICLE

TEXT REMINDERS IN PYREXIAL PAEDIATRIC PATIENTS (TRIPPP)

A RANDOMIZED CONTROLLED PILOT STUDY

Mohamed,Z Welzel, T

Author Information Mediclinic Cape Gate Emergency Centre,
c/o Okavango and Tanner Street, Brackenfell, Cape Town, South
Africa
+27 21 983 5911
zunaidmohamed@gmail.com

ABSTRACT

BACKGROUND

Improved discharge-communication systems remain essential for the delivery of high-quality emergency care. The relationship between the discharge process and patient-care outcomes has remained undetermined.

OBJECTIVES

The intent of the study was to assess whether text messaging of paediatric fever return criteria used as an adjunct to the routine discharge process in an Emergency Centre setting would impact patient-care outcomes as determined by the subsequent return for review and hospital admission if required.

The secondary outcome was to assess the caregiver's perception of the intended intervention.

METHODS

A two-arm parallel, randomised controlled pilot was conducted.

A total of 53 patients younger than 13 years, with a history of fever, presenting to a private hospital Emergency Centre in Cape Town, South Africa, not requiring hospitalisation at that time, were enrolled and randomly assigned to receive usual care - standardised verbal and printed paediatric fever discharge instructions - or to receive a series of text messages describing return criteria for paediatric fever, as an adjunct.

RESULTS

Patients under 13 years meeting the inclusion criteria (n=53) were randomly allocated to receive usual care discharge printed and verbal instructions (n = 27) or daily text messages describing paediatric fever return criteria for three days after discharge (n = 26) as an adjunct to usual discharge instructions.

Subsequent admission was reported for 2 (7, 69 %) of 26 patients recruited in the intervention group and for 1 (3,70 %) of the 27 patients recruited in the control group.

However, this observation could not be confirmed, as no significant difference in study groups was described and no statistically validated correlation with the intervention was observed (RR 0,96 OR 1 95% CI 0.47-2,37 P=1), thus no conclusion can be drawn from the data available.

No adverse events were reported.

CONCLUSIONS

Text messaging of return criteria, used to complement usual-care discharge instructions, in the management of paediatric patients presenting with fever, did not result in a significantly greater likelihood of subsequent hospitalisation for workup and further treatment.

The intervention was well received and considered to be useful by caregivers who also expressed satisfaction with the process implemented.

The sample size, however, was small as a result of slow accrual, and a larger multicentre trial is recommended in order to improve generalisability.

INTRODUCTION

The impact of digital interventions such as text message reminders are increasingly being researched in various healthcare settings. Recommended priorities that have been identified include the assessment of outcomes and potential benefits related to its use in child health. Pyrexial children with serious bacterial infections may be considered to be particularly vulnerable, especially when care transitions from health provider to caregiver.(1-4)

Transitions in care particularly at the point of discharge from a frequently fast paced, high patient volume Emergency Centre environment may, as a result of inadequate communication and coordination, be a period associated with increased risk for both patient and caregiver.(5)

Fever remains the most frequent presenting complaint in this vulnerable patient cohort, resulting in 20% of Emergency Centre visits. In Sub Saharan Africa, fever represents 6-30% of all practice visits. It is one of the most common reasons for hospital admission in the paediatric population.(6)(2)(7)

Fever can result from a number of conditions such as trauma, neoplastic conditions, drugs and autoimmune diseases, to name a few. However, in children in particular, fever commonly has an infectious origin, predominantly viral, self-limiting and benign. At the same time, it is most challenging to differentiate the cause for a fever in the young child. So paediatric febrile illness, especially under the age of 36 months, has been associated with numerous adverse outcomes affecting patients, caregivers and families including prolonged symptoms, impairment of activities and relapse.(6)(8)

A total of 5-10 percent of children with fever may have a serious bacterial infection without an easily clinically identifiable focus of infection. Serious bacterial infections are frequently challenging to diagnose resulting in late recognition. This may be as a result of symptoms that are subtle and clinical signs which may not easily be recognised, more frequently so in the younger patient, who also runs a risk of increased morbidity and mortality with rapid clinical deterioration.(2)(3)(4)

Various guidelines and risk stratification criteria have been developed in order to identify these patients who require further investigation and treatment. However, inconsistent application of the recommendations have been described as a result of, among other factors, practice setting and ongoing research involving biomarkers. Initial non-recognition of the underlying cause or clinical progression of the illness has been shown to be the most common reason for returning to the Emergency Centre in the case of paediatric fever. Research to date has emphasised the early identification of high-risk patients at the initial consultation rather than on improving health education delivery as a means to empower and encourage caregivers to return for reassessment as a further safety net. (6)(9)(10-16)

Text messaging used as part of the discharge process in order to communicate return criteria for paediatric patients with fever has until now remained unexplored.

It may prove to be a valuable intervention for the advancement of healthcare education delivery and the improvement of patient care outcomes. We thus sought to determine whether regular post-discharge text messaging of return criteria to the primary caregivers of febrile paediatric patients would result in increased vigilance for clinical review of the child's

condition, as determined by the need for subsequent admission when compared to those patients who received standard discharge instructions.

Secondly, we investigated the caregivers' view on the process implemented, including the level of satisfaction with respect to the intervention, its perceived usefulness and their current readiness to receive text messages. This was determined at a one-week follow up telephonic interview.

METHODS

We conducted a two-arm parallel, randomised controlled pilot at a private hospital Emergency Centre in Cape Town, South Africa.

Paediatric patients with fever presenting for acute care to the Mediclinic Cape Gate Emergency Centre at all hours and days of the week, who met the following pre-specified inclusion criteria, were prospectively and sequentially recruited into the study by the attending doctor or nurse, provided caregiver informed consent to participation was obtained. (Figure 1)

All patients screened over the eight month period starting on 1 March 2017 met the inclusion criteria.

The purpose of the study, its methods and implications were explained and enrolment facilitated. Participants were informed that some would be randomly selected to receive a daily text message for three consecutive days after discharge with a follow-up telephonic interview one week later.

Participants were assigned in a 1:1 ratio to either the intervention group or control group that would receive no text messages, utilising a computer generated randomisation sequence (using Microsoft Excel™, Redmont, USA) that had been determined by an independent biostatistician and transferred to sealed, opaque, identical, sequentially numbered envelopes which were used to assign participants to study arms. Successive patients who qualified for enrolment were assigned the next number envelope, locking them into one group or the other.

Individuals involved with recruitment and final data analysis were unaware of the participant's group assignments. Participants however were not masked to study group assignment, as the intervention required caregivers to either receive text messages and a follow-up phone call or not. It was essential that emergency care was instituted in the usual manner and that the recruitment process did not impair the expected standard of care.

All participants gave informed consent to participation in the study that was approved by the University of Cape Town Faculty of Health Sciences' Human Research Ethics Committee.

Interventions

The study was conducted as a randomised controlled trial with participants exposed to one of the following two conditions

- (1) Receipt of standard discharge-information brochures and verbal discharge advice related to paediatric fever, i.e. usual care comparison group

- (2) Receipt of standard discharge information brochures and verbal discharge advice related to paediatric fever and daily personalised text messages, over a three-day period, alerting parents of return criteria for paediatric fever, i.e., intervention group.

Return criteria included in the text message were based on recommendations regarded as standard level of evidence A (supported by at least two randomised controlled trials). (Table 1)(9)

The text message was sent to the caregiver by mobile phone on three consecutive days following the initial consultation.

International guidelines for digital health interventions of this nature recommend that the text message complement usual care practices and contain information to the same standard included in the discharge information pamphlets provided. It was also important that any potential follow-up care advised was in keeping with the reality of services available for access by the patient.(1)

Both the caregiver and the primary investigator, who was responsible for the follow-up telephonic interview, were thus not blinded to this intervention. Seven days after the initial consultation, the primary investigator phoned the enrolled participants (belonging to both the intervention and control groups) in order to conduct a standardised interview. The follow-up telephone calls, utilising a structured template questionnaire, were made in order to identify patients who subsequently may have been admitted to a hospital facility. The investigator also determined feedback regarding the intervention by asking caregivers to rate its perceived usefulness, their level of satisfaction regarding the process and their personal readiness to receive text messages on a scale from 1 to 10 (10 representing the most positive experience and 1 being the least). In addition, caregivers were afforded the opportunity to provide any additional insights or opinions which they felt they would like to share e.g., preferred timing and frequency of the intervention.

RESULTS

All patients screened met the inclusion criteria and none were excluded due to lack of mobile-phone ownership or living outside of network coverage. Fifty three patients were therefore included in the study.

Patients under 13 years meeting the inclusion criteria (n = 53) were randomly allocated to receive usual care discharge printed and verbal instructions (n = 27) or daily text messages describing paediatric fever return criteria for three days after discharge (n = 26) as an adjunct to usual discharge instructions. All caregivers approached agreed to enrol in the study.

Table 2. presents baseline characteristics for each group which appear to be distributed similarly across groups in the analytic sample. Sixteen subjects did not complete the study and were considered lost to follow-up (6 from the control group and 10 from the intervention group) as they were unreachable telephonically by the closure of the study. (Figure 1) No participants withdrew themselves from the study.

Subsequent admission was reported for 2 (7,69%) of 26 patients recruited in the intervention group and for 1 (3,70%) of the 27 patients recruited in the control group. However, no

significant difference in study groups was described and no statistically validated correlation with the intervention is observed (RR 0,96; OR 1; 95% CI 0,47-2,37;P=1), thus no conclusion can be drawn from the data available.

The small sample size and the number of participants lost to follow-up may have contributed to these findings.

Sixteen of the 26 participants who were allocated to the intervention group, and not lost to follow up, provided feedback regarding the intervention. Caregivers who had received the text message were asked to rate their experience of the service from 1 (least positive experience) to 10 (most positive experience) when considering its usefulness, satisfaction with the process and their readiness to receive the message. (Table 3)

In addition, caregivers were allowed to share any further thoughts or insight regarding the process. Based on the comments provided, there appeared to be a preference for receiving a single text message rather than repeatedly receiving the same message on further occasions. Caregivers also appeared to prefer receiving the message shortly after being discharged from the unit. There was no specific preference or need expressed for two-way messaging, and no adverse events were reported.

Figure 1. Enrolment flow diagram

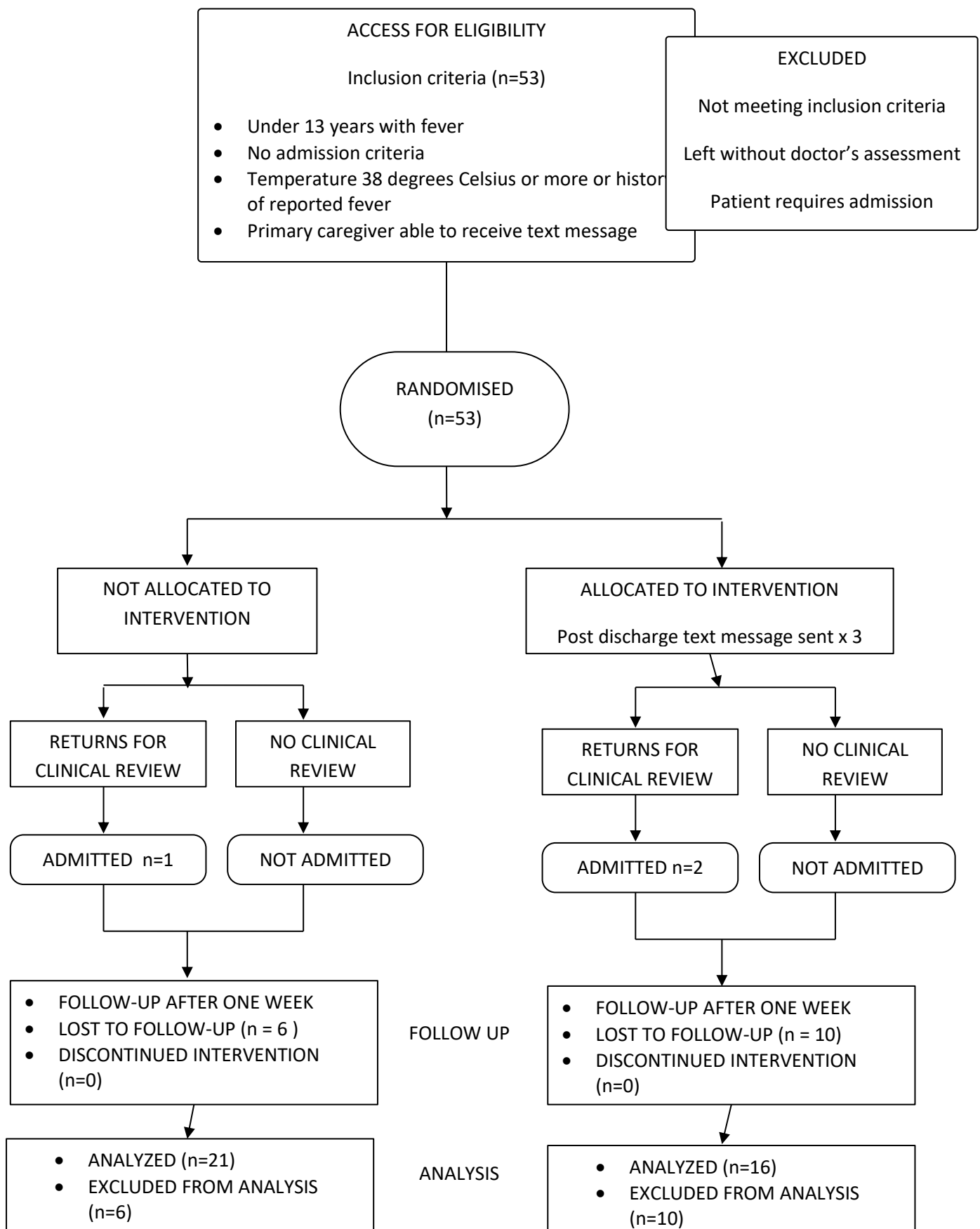


Table 1: Return Criteria based on recommendations described by Green and Geena et al.

1.	Signs of dehydration – sunken fontanelle/dry mouth/absence of tears/poor overall appearance/abnormal breathing.
2.	Development of a rash.
3.	The child has a seizure (fit)
4.	The child cries inconsolably (cannot be calmed down) or cries when touched.
5.	The child stops drinking or eating.
6.	The child's urine becomes dark in colour.
7.	The child's condition gets worse.
8.	Fever lasts longer than two days.
9.	One is concerned for any other reason.

Table 2 Characteristic by Group

CHARACTERISTIC		INTERVENTION GROUP (n=26)	CONTROL GROUP (n=27)
SEX	male	13	12
	female	13	15
AGE	mean (months)	38	38
	0 – 1 year	6	9
	1-5 years	15	13
	5 -10 years	5	3
	10-13 years	0	2
LANGUAGE	English	13	12
	Afrikaans	0	0
	Xhosa	0	0

Table 3 Follow-Up Telephonic Interview (10 item Likert scale) n=16

TELEPHONIC INTERVIEW QUESTIONS	MEAN RATING (1-10)
Was the intervention useful?	7.94 (CI 95% 0.87)
Were you satisfied with the process ?	8.44 (CI 95% 0.89)
Rate your readiness to receive the intervention	8.94 (CI 95% 0.68)

DISCUSSION

In April 2019 the World Health Organisation published its first evidence based guideline and recommendations for the implementation of health related digital interventions. The use of communication channels such as text messages – especially pertaining to the provision of child health was specifically identified as an area of priority. Interventions related to clinical outcome, improving patient education and the assessment of patient acceptability used in a manner to complement rather than replace fundamental components of practice have been recommended.(1)

The outcome measures considered in this study have incorporated both immediate (qualitative client perceptions) and distal (subsequent hospital admission) metrics.

Text message reminders in this study were well received and experienced to be acceptable by caregivers of pyrexial paediatric patients and feedback suggested promising levels of satisfaction and engagement. In addition, no adverse events or unintended effects were reported. These findings are in keeping with similar studies and suggest that text message reminders used as a digital intervention in this setting may be regarded as an impactful method of enhancing a patient's overall experience. It has been reported that using digital technology in this manner may potentially strengthen and positively influence the relationship with their health care provider allowing them to feel supported and encouraged with an increased sense of connectedness provided confidentiality is maintained.(1)(17)

At no time during the study were data privacy related concerns raised by caregivers of enrolled patients. The content of the text messages was standardized, evidenced-based and did not contain any information that may be considered sensitive or confidential. The absence of patient identifiers within the body of the text message, obtaining informed consent prior to the implementation of the intervention and ensuring that the message was only sent to the mobile number provided at the time of the consultation may have contributed to mitigating any privacy-related concerns.(18)

While it is necessary to recognise that patient perception and experience of the intervention is influenced by its content and format, the frequency and mechanism of delivery are also important contributors.

Promising outcomes using alternative message delivery mechanisms including voice, video and smartphone applications in order to provide discharge information also require further exploration. A study conducted by Ismail, McIntosh et al. reported improved parental understanding of paediatric fever discharge instructions when presented as an informational video at the point of Emergency Centre discharge. (19)

A possible extension of text message discharge instructions, and an area for further study – as suggested by one of our study participants – would be to incorporate links in the message to related websites or videos to provide additional information or different formats of providing the information. This may be a potential solution for population groups with lower levels of literacy. However, the cost implications for the user, i.e. access to phones with a browser and data speed and costs may impact its acceptability. Care should be taken not to further exclude and marginalise population groups from accessing health information and services.(1)

The most effective timing and frequency of text messages have not yet been determined and still require further investigation. According to a review by Kannisto et al., there is currently no recommended “dose”. Telephonic feedback during our follow-up interviews suggested that one message shortly after discharge appears to be the preferred “dosing” in this setting. This finding, however, would need to be verified as it was not included as a measurable outcome in our study. Furthermore, automated text-message software was not utilised resulting in a variation in the timing of the sent message. (20)

Subsequent hospital admission of patients, as a distal outcome measure in this trial, may be influenced by a number of complexities and constraints. Firstly, severe illness resulting in hospitalisation may have presented beyond the one week follow-up interview and as a result, would then potentially not have been included in the outcome of the study. Furthermore, the decision for hospitalisation both at the initial Emergency Centre visit and follow-up consultation, may be influenced by a number of non-clinical external factors including hospital capacity and parental anxiety associated with the clinical presentation.

Robust methodology throughout this prospectively designed study has been considered essential and minor protocol violations related to task assignment and implementation are unlikely to impact individual outcomes. All staff involved with the enrolment and final data analysis remained blinded to participant group allocation. This however was not possible for the participants themselves given the nature of the intervention. No unintended exposure to the intervention by the control group was reported at the follow up telephonic interview, thus reducing the risk of possible performance bias.

Although methods used for randomization and allocation concealment contributed to minimizing potential selection bias, the baseline characteristics recorded for the trial did not take into account potential co-morbid illnesses like HIV and Tuberculosis prevalent to South Africa. These illnesses, however, are considered a less frequent presentation at the study site and as they had not been accounted for, their impact in this study remains unclear. (7)

The study was conducted at a single private healthcare facility, potentially only representing a singular view of the South African context. The population group under investigation was able to access both mobile phone technology and private healthcare services, including ambulatory specialist paediatric care during daily operational work hours. Additional factors such as network coverage, cost and population literacy were not included in the evaluation which may impact the generalizability of the investigation conducted. A larger trial incorporating multiple private and public Emergency Centres would allow for a broader population sample. In this way variations in aetiology, clinical presentation, health status and demographic profile may be more extensively represented thus enhancing the overall external validity of the research.

Despite broad eligibility criteria and the allowance for usual standard of care clinical practice, screening and enrolment of patients to the study was slow and erratic, resulting in a relatively small sample size which would need to be considered should any further extrapolation of the findings be undertaken.

Although a sample size calculation was performed, the limited availability of applicable baseline and event rate data made obtaining a statistically significant estimation a challenge. Furthermore the ease of recruitment in the private healthcare setting was unknown. While

not the primary consideration of a pilot study, these factors would need to be taken into consideration in the methodology and design of future similar trials.

Successful patient recruitment was negatively impacted by the reliance on largely non-permanent locum staff not familiar with the study protocol, especially after-hours and on weekends, when pyrexial paediatric patients present most frequently. Incorporating additional centres with a greater permanent staff compliment, enlisting the department's nursing personnel as additional study advocates and ensuring adequate orientation and training prior to data collection should enhance the screening and enrolment of participants.

In addition, successful completion of the interview, on the whole was problematic and challenging. Multiple phone calls were often required in order to reach caregivers and the number of participants ultimately lost to follow up as a result was higher than anticipated. Furthermore, being unreachable by phone may presumably have been associated with a failure to receive the text messages in the intervention arm of the study. Loss, theft, sharing of mobile phones or changing contact telephone numbers may impact the delivery of the intended intervention and are possible limitations associated with this form of communication. For this reason, investigating improved ways to ensure contact with patients who may have restricted or shared access to mobile devices have been recommended. (1)(21)

Infrastructural constraints such as network connectivity and access to electricity may also impact message delivery and patient contact. In order to address this observation, future studies should complement the evaluation of primary outcome measures with concurrent assessment of the effectiveness of the intervention in terms of its delivery. (1)(17)

CONCLUSION

Although the relationship between the discharge process and patient care outcomes specifically pertaining to the Emergency Centre management of paediatric fever - remains undetermined, utilizing text messaging as a complementary minimal risk intervention may be considered a potentially valuable contributor to advancing healthcare education delivery for optimising transitions in care, specifically at the point of Emergency Centre discharge.

The trends noted in this pilot study are informative and encouraging and underscore a number of pertinent observations and recommendations related to digital interventions in healthcare. We are able use the information and findings to determine the feasibility to conduct similar future sufficiently powered studies and gain valuable insight regarding appropriate methods, procedures and effect size estimates required for their design.

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SECTION C: ADDENDA

ADDENDUM 1

INCLUSION CRITERIA

- ALL PATIENTS UNDER THE AGE OF 13 YEARS WHO PRESENT WITH FEVER OR A HISTORY OF FEVER ACCOMPANIED BY PARENTS OR PRIMARY CARE GIVER
- PATIENT IS STABLE FOR DISCHARGE IE NOT ADMITTED TO HOSPITAL
- TEMPERATURE 38 DEGREES CELCIUS OR MORE AS MEASURED TYMPANICALLY IN THE EMERGENCY CENTRE OR A PRESENTING HISTORY OF FEVER
- THE PARENT OR PRIMARY CARE GIVER IS IN THE POSSESSION OF A PERSONAL MOBILE PHONE ABLE TO RECEIVE TEXT MESSAGES
- CONSENT OBTAINED FROM PARENT / PRIMARY CAREGIVER

ADDENDUM 2
EXCLUSION CRITERIA

- PATIENTS THAT HAVE LEFT THE UNIT WITHOUT BEING SEEN ASSESSED BY THE DOCTOR
- PRIMARY CARE GIVER UNWILLING TO CONSENT
- ADMISSION OF PATIENT IS REQUIRED
- CAREGIVER UNABLE TO READ EITHER ENGLISH, AFRIKAANS OR XHOSA

ADDENDUM 3

CONSENT FORM

PARTICIPANT INFORMED CONSENT DOCUMENT AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE : Text Reminders in Pyrexial Paediatric Patients (TRIPPP) – A Randomised Control Trial

LAY TITLE: To determine if- alerting parents by means of text messaging - of symptoms to look out for in children with fever, would result in having him/her reassessed and in this way prevent more serious disease

STUDY PHYSICIAN: Dr Z Mohamed

STUDY SITE: Mediclinic Cape Gate Emergency Centre

TELEPHONE NUMBER: 021 983 5911

INTRODUCTION

Your participation in this research study is voluntary.

To help you decide if you want to be part of this study, the risks and possible benefits of the study are described in this document so that you may make an informed decision.

This process is known as informed consent.

You may have a copy of this form to review at your leisure or ask advice from others.

The study doctor/investigator will answer any questions that you may have about this study

Should the form contain words or phrases that you may not understand please ask the study doctor to provide an explanation.

After reading this consent form, if you would like to participate, you will be asked to sign the form.

You will be given a signed copy of your consent form to take home and keep for your records.

WHAT IS THE PURPOSE OF THE STUDY

You are invited to participate in a study which will determine if alerting parents - by means of text messaging via your cellular phone - of symptoms to look out for in children with fever. We want to determine if such a text is helpful in reassuring and/ or preventing more serious disease.

HOW LONG WILL YOU BE INVOLVED IN THIS STUDY?

If you agree to participate in the study, your length of stay in the Emergency Centre should not be affected and assessment and treatment will continue as usual. At one week (seven days) after your Emergency Centre visit you will need to participate in a brief follow up telephone call.

WHAT DO I HAVE TO DO?

If you agree to participate in the study, you will be required to do the following as part of your participation

- Sign this informed consent form
- Participate in a short follow up phone call seven days after treatment

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS OF TAKING PART IN THE STUDY?

The assessment and treatment provided will not differ from the usual treatment provided. Receiving regular text messages about what to look out for regarding your child's health may cause you to be unusually anxious about his /her condition.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

Severe Bacterial infection and serious illness is easily missed clinically in children with fever. Having an increased awareness of possible warning signs associated with fever, may prompt a re-evaluation and prevent any further serious illness.

The information provided by text message would empower you as a parent to ensure that your child returns for re-evaluation to prevent his/her condition from worsening.

The information that we get from this study may help us to better treat future patients who have the same condition. (I.e. children with fever)

IS THERE FINANCIAL COMPENSATION PROVIDED?

You will not be paid to participate in this trial.

WHO HAS REVIEWED THIS STUDY?

The trial has been approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee and has been structured in accordance with the Guidelines of Clinical trials and Ethics in Health Research published by the Department of Health and the Declaration of Helsinki. The study has also been approved by the Emergency Medicine Department Research Council and Mediclinic Clinical Department.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR NEED ADDITIONAL INFORMATION?

You are encouraged to ask questions. You should feel free to talk to the nurse or study doctor at any time during the study and they will try to explain anything that you do not understand. The study will be done under the supervision of Dr Z Mohamed whose address is: Mediclinic Cape Gate Emergency Centre co Okavango and Tanner Street Brackenfell, and telephone number 021 9835911

IS PARTICIPATION VOLUNTARY?

Your participation in this study is voluntary. You may stop participating in this study at any time and without giving a reason. Your decision not to take part in this study or to stop your involvement will not affect your medical care or any benefits to which you are entitled. ***If you decide to stop taking part in this study you should inform your study doctor accordingly.***

Chief Investigator: Dr Z Mohamed

Supervisor: Dr T Welzel

Thank you for agreeing to participate in this trial. Please sign below to indicate that you have read and understand the requirements for your participation.

- I understand the requirements for my participation in this trial
- I understand that my participation is voluntary .and that I may withdraw from this study at any time without penalty
- The risks and benefits of participating in the trial have been explained to me and I understand them
- I understand that I will be allocated to one of two groups A or B and that if allocated to group B , I shall receive text messages relating to return criteria for paediatric fever
- I can request further information about the results of this study by submitting my request in writing to the chief investigator.

Signature :

Participant's Full name:

Address:

Telephone number:

Email address:

ADDENDUM 4

RECRUITMENT FLOW

PAEDIATRIC FEVER TRIAL

PATIENT MEETS TRIAL CRITERIA (SEE INCLUSION CRITERIA)



ENSURE THAT STANDARD TREATMENT
IS NOT DELAYED

- DISCUSS CONSENT
- ENSURE THAT CONSENT HAS BEEN READ AND UNDERSTOOD
 - DOCUMENT THE CONSENT



BEFORE DISCHARGE ENSURE THAT :

- CONSENT OBTAINED AND COPY GIVEN TO PATIENT
- CARE GIVER'S MOBILE TELEPHONE NUMBER OBTAINED

ADDENDUM 5

JOURNAL AUTHOR GUIDELINE (SOUTH AFRICAN MEDICAL JOURNAL)

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc) that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
• E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the \pm symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

ADDENDUM 6

CONSORT CHECKLIST



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	_____
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	_____
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	_____
	2b	Specific objectives or hypotheses	_____
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	_____
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	_____
Participants	4a	Eligibility criteria for participants	_____
	4b	Settings and locations where the data were collected	_____
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	_____
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	_____
	6b	Any changes to trial outcomes after the trial commenced, with reasons	_____
Sample size	7a	How sample size was determined	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines	_____
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	_____
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	_____
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	_____
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	_____

CONSORT 2010 checklist

Page 1

ADDENDUM 7

CONSORT CHECKLIST CONTINUED

		assessing outcomes) and how	_____
	11b	If relevant, description of the similarity of interventions	_____
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_____
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	_____
Recruitment	13b	For each group, losses and exclusions after randomisation, together with reasons	_____
	14a	Dates defining the periods of recruitment and follow-up	_____
	14b	Why the trial ended or was stopped	_____
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	_____
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	_____
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	_____
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	_____
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____
Other Information			
Registration	23	Registration number and name of trial registry	_____
Protocol	24	Where the full trial protocol can be accessed, if available	_____
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	_____

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

ADDENDUM 8

HREC APPROVAL



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: sumayah.arnedien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

17 October 2016

HREC REF: 857/2015

Dr T Welzel
Division of Emergency Medicine
Room J-46.56
OMB

Dear Dr Welzel

PROJECT TITLE: TEXT MESSAGING IN PYREXIAL PAEDIATRIC PATIENTS (TRIPPP); A RANDOMISED CONTROL TRIAL (M.Phil-candidate-Z Mohamed)

Thank you for your response letter addressing the issues raised by Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th October 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student, Dr Z Mohammed will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

HREC 267/2016

ADDENDUM 9
TURN IT IN REPORT

**TEXT REMINDERS IN PYREXIAL
PAEDIATRIC PATIENTS (TRIPPP)**
A RANDOMIZED CONTROLLED PILOT STUDY

by
Zunaid Mohamed

Match Overview			
25%			
1	Submitted to University...	4%	>
2	repository.up.ac.za	1%	>
3	open.uct.ac.za	1%	>
4	www.jmir.org	1%	>
5	www.experts.scival.com	1%	>
6	Odeny, Thomas A., Rob...	1%	>
7	Submitted to Royal Coll...	<1%	>
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ADDENDUM 10

TEXT MESSAGE

Following your recent visit to the Mediclinic Cape Gate Emergency Centre with your child who had fever – please monitor his/her condition regularly and return to the Emergency Centre or nearest healthcare facility if any of the following is present

- A new rash develops
- He/she has a fit (jerk movements of the arms and legs)
- Your child becomes very irritable and continues cry despite attempts to calm him/her – unable to console
- Poor appetite (very little eating or drinking)
- The urine becomes dark in colour
- The condition becomes worse
- The fever lasts longer than 2 days
- Your child appears dehydrated-dry mouth/no tears/appears weak/abnormal breathing
- Any other concerns that you may have regarding your child's condition

Please note that there is no additional account for the follow up consultation if returning to Mediclinic Cape Gate Emergency Centre